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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/684,199	10/10/2003	Malcolm D. McGinnis	13525 C1	5067

7590 05/02/2006

David A. Kalow, Esq.
Kalow & Springut LLP
488 Madison Avenue, 19th Floor
New York, NY 10022

EXAMINER	
TUNG, JOYCE	

ART UNIT	PAPER NUMBER
1637	

DATE MAILED: 05/02/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/684,199	MCGINNIS ET AL.	
	Examiner	Art Unit	
	Joyce Tung	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-14 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-14 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date ~~3/24/05~~ 3/8/05
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Double Patenting

1. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. Claims 1-14 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-14 of U.S. Patent No. 6,635,419. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims 1-14 are drawn to a method for determining a sequence of one or more nucleotides in a target polynucleotide which has the same method steps as compared with claims 1-14 of U.S. Patent No. 6,635,419 except that claims 1-14 of U.S. Patent No. 6,635,419 requires one detectable breakdown product from the labeled 3'-nucleotide terminator which elutes before non-extended primer so as not to overlap in elution with the primer extension product(s). Thus, the instant claims 1-14 are a genus and claims 1-14 of U.S. Patent No. 6,635,419 are species.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

4. Claims 1-4 and 6-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Grossman et al. (5,580,732, issued December 3, 1996).

Grossman et al. disclose DNA sequencing which is carried out by providing binding polymer/polymer chain conjugates as sequencing primers in the standard chain termination approach to DNA sequencing (See column 30, lines 8-11). The polymer chain should not effect hybridization reaction (See column 8, lines 44-45).

Grossman et al. do not explicitly disclose that each target-specific primer contains a mobility-reducing moiety, which does not bind the target.

Grossman et al. disclose the polymer chain has a unique ratio of charge/translation frictional drag in the non-sieving liquid medium (See column 3, lines 24-31). The polymer chain

can be built on a sequence-specific binding polymer (See column 11, lines 46-52). The polymer chain imparts to its probe, a ratio of charge/translational frictional drag, which is distinctive for each different sequence probe (See column 11, lines 58-60). Fluorescent dyes are attached to the chain terminating nucleotides (See column 22, lines 19-20). The polymer chain has different size and/or charge differences can be finely resolved by electrophoresis in a non-sieving medium (See column 12, lines 3-8). The DNA fragment is labeled by way of radioactive nucleoside triphosphate precursors (See column 21, lines 17-19).

Grossman et al. also do not disclose the separating the primer extension products under denaturing conditions in a sieving matrix.

However, Grossman et al. disclose that the details of each steps varies according to several factors well known in the art, including the nature of the labeling means for identifying the different chain-termination nucleotides, and the means for separating the different DNA fragment population (See column 21, lines 63-67). Especially, the definition of the sieving matrix is defined as "crosslinked or non-crosslined medium polymers" (See the specification, pg. 12, lines 1-5) which are known in the art. Thus, it directs one of ordinary skill in the art to use any means for separating the primer extension products as claimed.

One of ordinary skill in the art at the time of the invention would have been motivated to apply the method of Grossman et al. for determining a sequence of one or more nucleotides in a target polynucleotide because the method of Grossman et al. applied the polymer chain which is conjugated to a sequence-specific binding polymer (See column 11, lines 46-52) and the polymer chain allows for effective fraction of a plurality of oligonucleotide, all of which have similar or identical sizes (See column 20, lines 31-36). It would have been prima facie obvious to apply the

method of Grossman et al. for determining a sequence of one or more nucleotides in a target polynucleotide.

5. Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Grossman et al. (5,580,732, issued December 3, 1996) as applied to claims 1-4 and 6-14 above, and further in view of Levis et al. (5,210,412, issued May 11, 1993).

The teachings of Grossman et al. are set forth in section 4 above.

Grossman et al. do not disclose that the reacting is conducted in the presence of four different 3'-nucleotide terminators which are each complementary to a different nucleotide base-type and each contains a distinguishable fluorescent label that identifies the base-type of the terminator.

Levis et al. disclose that radioactive labeled products from each of the four dideoxy sequencing reaction are denatured to separate the newly synthesized DNA from the template and then electrophoresed in adjacent lanes on a polyacrylamide gel such that the DNA product are separated based on their chain length (See column 2, lines 13-18). The fluorescent terminated DNA products are also run on a polyacrylamide gel and the discrete-length products are detected near the bottom of the gel by their emitted florescence (See column 2, lines 37).

One of ordinary skill in the art at the time of the instant invention would have been motivated to apply the teachings of Levis et al. to the method of Grossman et al. for determining a sequence of one or more nucleotides in a target polynucleotide because the teachings of Levis et al. provide faster sequencing and accurate sequencing (See column 2, lines 40-49). It would have been prima facie obvious to apply the teachings of Levis et al. into the method of Grossman

et al. for determining a sequence of one or more nucleotides in a target polynucleotide as claimed.

Summary

6. No claims are allowed.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joyce Tung whose telephone number is (571) 272-0790. The examiner can normally be reached on Monday - Friday, 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571 272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Joyce Tung J. T.
April 26, 2006

KENNETH R. HORLICK, PH.D
PRIMARY EXAMINER
5/1/06